

DRAFT/UNAPPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

December 1, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15 a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT: Melvin L. Boone, Sr. (arrived 9:18 a.m.)
Michael I. Elliott
Freeda Cathcart
Ryan K. Logan
Rafael Saenz
Rebecca Thornbury
Ellen B. Shinaberry
Jody H. Allen
Sheila K. W. Elliott (arrived 9:18 a.m.)

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Lisa Hahn, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Sharon Davenport, Administrative Assistant

STAFF ABSENT: J. Samuel Johnson, Jr., Deputy Executive Director

QUORUM: With eight members present initially, a quorum was established.

APPROVAL OF AGENDA: An amended agenda was provided as a handout for the members, staff, and the public. The following two topics were included on the amended agenda: under Old Business, a request from VPhA to amend guidance document 110-36 *Compliance with USP Standards for Compounding* and under new Business, consideration for mandatory continuing education for pharmacists on a specific topic in 2016.

MOTION: The Board voted unanimously to approve the amended agenda as presented in the handout. (motion by Shinaberry, second by Saenz)

APPROVAL OF MINUTES: The Board reviewed draft minutes in the agenda packet for:

- September 29, 2015, Public Hearing for Scheduling Certain Chemicals
- September 29, 2015, Full Board Meeting

- September 29, 2015, Panel Formal Hearings
- September 30, 2015, Inspection Special Conference Committee
- November 3, 2015, Regulation Committee

MOTION:

The Board voted unanimously to approve the minutes as presented for the meetings held between September 29, 2015 and November 3, 2015. (motion by Allen, second by Logan)

PUBLIC COMMENTS:

No comment was provided to the Board.

DHP DIRECTOR'S REPORT:

Cynthia Warriner introduced the newly-appointed Chief Deputy Director of DHP, Lisa Hahn, who provided the Director's report in place of David Brown, D.C who was attending another meeting outside of the office. Ms. Hahn provided comment that the new board member training as well as board member development day went very well. Ms. Hahn elaborated on the additional training that DHP has been providing staff regarding employee hiring, employee work performance reviews, and supervisor training. Ms. Hahn also spoke of the Healthcare Workforce Data Center and the surveys conducted mainly during renewal of licensure and how they will be used in an aggregate manner in the near future to educate high school students about careers in healthcare.

**REPORT ON APPALACHIAN
COLLEGE OF PHARMACY:**

Susan Mayhew, Dean of Appalachian College of Pharmacy provided a report via Polycom to the board on recent school activities. A handout summarizing her report was also provided to the members, staff, and public. The College has graduated over 500 students who are practicing throughout the United States. Dean Mayhew indicated that between 40-50% of the graduates remain in the Appalachian region. In 2014 the College had Virginia's highest pass rate on the NAPLEX examination. The College has Virginia's only three-year accelerated Doctor of Pharmacy program.

The College recently opened its Mountain Care Center delivering pharmaceutical care to the indigent in the region. The College has begun a global health elective, started a community residency program as well as a post doctorate program. The school also just completed a re-accreditation through ACPE and has an upcoming accreditation visit from the Southern Association of Colleges of Pharmacy.

**REPORT ON HAMPTON
UNIVERSITY COLLEGE OF
PHARMACY:**

Wayne Harris, Dean, and Anand Iyer, Assistant Dean of Academic and Student Affairs from Hampton University College of Pharmacy appeared in-person and provided a report to the board on recent school activities. Dean Harris reported that the College admitted its first class in 1998 and has graduated over 600 PharmD candidates. Current enrollment is approximately 250 students with possible growth in the future. The site visit for ACPE in November 2014 went well and the accreditation was continued for a time period of eight years. The school has an ongoing curriculum review to build for the future and includes establishing the Hampton University center of excellence which will focus on providing medication therapy management to medically underserved clinics.

Four faculty members at The College currently have research grants through the National Institutes of Health (NIH). He reported there is an interest in increasing the school's involvement in research. Dean Harris is currently a co-director of a minority men's health initiative, funded NIH to address minority health disparities.

REGULATORY ACTIONS:

- REGULATORY
UPDATE:

Ms. Yeatts provided a chart of regulatory actions as a handout. Emergency regulations for outsourcing facilities and Practitioner of the Healing Arts are currently at the Governor's office. There are two actions that are at the Department of Budget and Planning and those are the collection sites for disposal of unused drugs and the repackaging at PACE sites. In addition there are two actions that are in a public comment period, one of which the public hearing was held just prior to this Board meeting. Those public comment period for the prohibition against incentives to transfer prescriptions ends 12/16/15 and the comment period for addressing hours of continuous work by pharmacists ends 1/29/16.

- REGULATION
COMMITTEE REPORT
ON ISSUANCE OF CSR
TO MEDICAL OFFICE
BUILDING:

Ms. Shinaberry reported that the Regulation Committee determined at its November 3, 2015 meeting to recommend that the board not issue one controlled substances registration certificate (CSR) to authorize multiple medical clinics located in the same medical office building with shared ownership to stock drugs in multiple locations throughout the building. Based on concerns for oversight, it recommended that board staff continue to issue CSRs to individual clinics that maintain their own stock of drugs for their own use. Mr. Saenz recused himself from the discussion and voting since the request for a single CSR came from his employer.

VOTE

The Board voted unanimously to accept the recommendation of the Regulation Committee and not authorize staff to issue one controlled substances registration certificate (CSR) to authorize multiple medical clinics located in the same medical office building with shared ownership to stock drugs in multiple locations throughout the building. (Saenz recused)

- REQUEST FOR
RULEMAKING TO
ALLOW "BACK-UP"
PHARMACY TO
DISPENSE FIRST FILL
OF PRESCRIPTION
WITHOUT
NECESSITATING
TRANSFER OF
PRESCRIPTION:

Ms. Yeatts advised that this request should be treated as a petition for rulemaking which requires a publication of the request and a 21-day public comment period prior to the Board considering the matter. Therefore, this matter will be deferred to a later date.

OLD BUSINESS:

- REQUEST FROM VPHA TO AMEND GUIDANCE DOCUMENT 110-36:

Ms. Juran provided a handout on the issue and reminded the board members that this issue was discussed at the September board meeting and staff was tasked with researching the issue further. Ms. Juran contacted USP experts who confirmed that USP allows for alternative methods of sterility testing. Since Virginia law allows compliance with USP, alternative methods of sterility testing are allowable. Ms. Shinaberry pointed out that the first two sentences in the draft answer to #39 in the guidance document may need to be adjusted in the future based on proposed revisions to USP <797>. Ms. Allen agreed and pointed out that proposed revisions may take up to two years or longer to be adopted by USP.

MOTION:

The Board voted unanimously to amend Guidance Document 110-36 as presented in the handout which provides guidance in a new question #39 regarding the use of a microbiological method alternative to compendial methods used. (motion by Cathcart, second by S. Elliott)

NEW BUSINESS:

- NEED GUIDANCE FOR NURSES PUMPING METHADONE TAKE HOME BOTTLES:

Ms. Juran referenced the request from a narcotic treatment program (NTP) in the agenda packet. The NTP would like to know if nurses can pump, i.e., prepare methadone take home bottles for patients under pharmacist supervision. Board counsel advised he would need to research the statute regarding duties of a pharmacy technician and if these duties could be performed by a nurse in a NTP under pharmacist supervision.

ACTION ITEM:

The Board recommended that the matter regarding a need for guidance for nurses pumping methadone take home bottles be deferred to the March board meeting to allow counsel time for researching the issue.

- REQUEST TO AMEND GUIDANCE DOCUMENT 110-8, PRESCRIPTIVE AUTHORITY IN VIRGINIA:

Ms. Yeatts stated that there are two changes to this document on prescriptive authority. The first change is that optometrists may now prescribe hydrocodone in combination with acetaminophen products which are now Schedule II and a regulatory change for physician assistants regarding the co-signature of prescriptions in certain schedules. Since the change for optometrists is a legislative change that has already been passed and the second change for PA's prescribing rules is a regulatory change that is likely to be effective on January 15, 2016, Ms. Yeatts suggested that the Board either have two separate motions or one motion with two parts. The Board agreed to have two separate motions as this would be clearer in the event the regulatory change did not occur on January 15, 2016.

MOTION:

The Board voted unanimously to amend Guidance Document 110-8 as presented to reflect the legislative change in 2015 that permits optometrists to prescribe hydrocodone in combination with

acetaminophen products. (motion by S. Elliott, second by Cathcart)

MOTION:

Contingent upon the Board of Medicine regulatory amendment becoming final January 15, 2016, the Board voted unanimously to amend Guidance Document 110-8 as presented which would advise that the name of the supervising physician be included on a Schedule II-V prescription written by a physician assistant. (motion by Allen, second by Boone)

- **AMEND GUIDANCE DOCUMENT 110-4, CONTINUING PHARMACY EDUCATION GUIDE:**

Ms. Juran indicated that there are some exceptions in law that appear to create confusion for licensees as to when they must renew their license or registration and if they must obtain hours of continuing education. Staff has recently answered numerous questions on this subject and recommends that the board amend Guidance Document 110-4 to provide clarity on the subject. A handout was provided with staff's suggested amendments for the guidance document. Ms. Shinaberry recommended the question and answer on page 3 of the handout be changed to read, "Q. I've taken a course near the end of the year and didn't get my certificate until the next calendar year. How are the hours applied? A. CE credit is awarded based on the date the certificate is issued or the date the hours are awarded. Live courses are counted on the date of attending the course." Prior to voting, a corrected version of the handout was also provided which included staff's draft language for two additional frequently asked questions.

MOTION:

The Board voted unanimously to amend the question and answer on page 3 of the corrected handout to read, "Q. I've taken a course near the end of the year and didn't get my certificate until the next calendar year. How are the hours applied? A. CE credit is awarded based on the date the certificate is issued or the date the hours are awarded. Live courses are counted on the date of attending the course." and to otherwise amend the guidance document as presented in the corrected handout provided during the meeting. (motion by Saenz, second by Shinaberry)

- **CONSIDER MANDATORY CE FOR PHARMACISTS ON A SPECIFIC TOPIC IN 2016:**

Ms. Warriner discussed the possibility of continuing the opioid use and abuse CE topic or possibly choosing another pertinent topic for mandatory continuing education for pharmacists based on the allowance in §54.1-3314.1 J. Mr. Saenz asked the possibility of reaching out to the Department of Health or other agency to determine if there are other public health issues that may be problematic. Ms. Allen commented that we may want to see results from a continuing education audit from 2015 prior to choosing another mandatory topic for continuing education. Mr. Elliott agreed with Ms. Allen. Ms. Shinaberry stated that this one time mandatory CE was intended to educate on this specific topic and did not see a need to continue it in 2016.

MOTION:

The Board voted unanimously to not have a mandatory topic of continuing education for pharmacists in 2016.

- AMEND GUIDANCE DOCUMENT 110-27, PHARMACIST-IN-CHARGE RESPONSIBILITIES

Ms. Juran reported that staff occasionally receives questions on PIC responsibilities and recommends the board consider amending Guidance Document 110-27 to provide clarity on the subject.

MOTION:

The Board voted unanimously to amend Guidance Document 110-27 as presented in the agenda packet which clarifies on page two of the document that the pharmacy permit application must indicate the effective date the pharmacist intends to assume the role as PIC, strikes the sentence regarding board approval of the signed application, and clarifies that the incoming PIC inventory must be taken prior to opening for business on the date the pharmacist first assumes the role as PIC. (motion by Logan, second by Saenz).

- PRESENTATION ON THE HEALTH PRACTITIONERS' MONITORING PROGRAM (HPMP):

Janet Knisely, Ph.D and Sherman Master, MD with the Virginia Commonwealth University presented to the Board information on the Health Practitioners' Monitoring Program including the mission of the program and the goals to achieve their mission. Some of the topics discussed during the presentation were the inception of the program, the intake process, toxicology testing process, case management, ongoing monitoring and reviewing the statistics of the program. A handout of their Power Point slides was provided.

- RECONSIDER DATE FOR MARCH 2016 FULL BOARD MEETING:

The Board unanimously agreed to change the date of the March 2016 Board meeting from March 29, 2016 to March 25, 2016 due to a scheduling conflict with Ms. Juran.

- SET DATES FOR JANUARY AND MARCH REGULATION COMMITTEE MEETINGS:

Ms. Juran indicated that the date for the Regulation Committee meeting had recently been scheduled for January 5, 2016 and that no further action was needed for that meeting. The Board unanimously agreed to schedule the March Regulation Committee meeting on March 24, 2016.

REPORTS:

- Chairman's Report

Ms. Warriner informed the board that she had received a note from Dean DiPiro, Dean of the Virginia Commonwealth University School of Pharmacy congratulating the Board on receiving the NABP Fred T. Mahaffey award earlier this year. Additionally, she congratulated Ms. Logan for recently being appointed to the Board of Health Professions and thanked Ms. Shinaberry for her past participation on this board. Lastly, she thanked Ms. Thornbury for representing the board during the recent ACPE accreditation site visit at the Appalachian College of Pharmacy.

- Report on Board of Health Professions

Mr. Logan was appointed to the Board of Health Professions and since his appointment the board of health professions has not had a meeting.

- Report on ACPE visit to Appalachian College of Pharmacy

Ms. Thornbury provided a report on the ACPE site visit to the Appalachian College of Pharmacy. Ms. Thornberry stated it was a very positive experience and very informative. She was thankful for the opportunity to attend this site visit and encouraged other board members to do so as the opportunity arises.

- Report on licensure program

In Mr. Johnson's absence, Ms. Juran provided the licensure report. She indicated the board currently licenses 36,838 individuals and facilities. The Board issued 763 licenses and registrations for the period of September 1, 2015 through November 29, 2015. Inspectors conducted 356 facility inspections including 154 routine inspections of pharmacies: 36 (23%) resulted in no deficiency, 53 (35%) with deficiencies and 65 (42%) with deficiencies and a consent order. Ms. Shinaberry commented that she noticed approximately 30% of all major deficiencies involved sterile compounding.

ACTION ITEM:

Additionally, Ms. Shinaberry requested if staff could break out the hospital pharmacy from the community pharmacy statistics in the licensure report. Ms. Juran indicated this would have to be done manually, but that she would look into the feasibility of it.

- Report on disciplinary program

Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report comparing the case stages between the four report dates of March 24, 2015; June 12, 2015; September 28, 2015; and November 30, 2015. For the final date, she reported that there were no cases at the entry stage; 69 at the investigation stage; 158 at the probable cause stage; one at the administrative proceedings division stage; three at the informal stage; three at the formal stage; and 105 at the pending closure stage.

Further, Ms. Reiniers-Day discussed the importance of having the Special Conference Committees attend informal conferences on a monthly basis to avoid a backlog of informal conferences, but also cases for presentation. She thanked Ms. Allen and Mr. Boone for attending on November 23rd when two informal conferences were held and 54 cases were presented.

- Executive Director's report

Ms. Juran provided a handout which highlighted the meetings she or staff has attended since the last full board meeting. She reported Mr. Johnson and Ms. O'Halloran convened a job analysis meeting recently for the pharmacy technician exam. Additionally, Ms. O'Halloran attended training on sterile compounding offered by NABP for board staff and inspectors. She provided a brief update on staffing issues and mentioned two upcoming presentations that she will offer in the next month.

CONSIDERATION OF CONSENT ORDERS

Closed Meeting:

Upon a motion by Ms. Thornbury, and duly seconded by Ms. Elliott, the Board voted 10-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of two Consent Orders. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran, James Rutkowski and Loni Dickerson attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

Reconvene

The Board voted unanimously that only public business matters lawfully exempt from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

MOTION:

Upon a motion by Ms. Allen and duly seconded by Mr. Elliott, the Board voted 10-0 in favor of accepting the Consent Orders as presented by Ms. Reiniers-Day in the matters of Denise A. Coffman and Sandy Rivers, pharmacy technicians.

ADJOURN:

With all business concluded, the meeting concluded at approximately 1:40 pm.

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director